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EXAMINER

HM12/0316

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ART UNIT

PAPER NUMBER

1648

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/362,394

Applicant(s)

Oon et al.

Examiner

Donna C. Wortman, Ph.D.

Group Art Unit

1648



☒ Responsive to communication(s) filed on Jul 28, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-18 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1648

Claims 1-18 as originally filed are pending and under examination.

The disclosure is objected to because of the following informalities: The disclosure at least at page 9, line 19; at page 12, line 28; and at page 14, line 32 improperly makes reference to a claim by number. There may be other such references as well. Applicant is requested to review the specification and to delete any reference to claim numbers and, if necessary, to amend the specification to include any material that is only presented as part of a claim.

Appropriate correction is required.

Claims 2, 15, and 18 are objected to because of the following informalities:

Claim 2, last line, recites "the said ..." which expression is redundant. Claim 15, line 6, also recites "the said ...". In claims 2 and 15, either "the" or "said" should be deleted.

Claim 18 is of improper form because it has improper punctuation; a claim should have a period only at the end. Claim 18 is also improper because it recites a complete sentence within the claim (lines 4-9).

Appropriate correction is required.

The claims are generally rather unclear. Some examples of the lack of clarity are addressed below.

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1648

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clear how many synthetic oligonucleotides represent a "set" as recited. Further, the claim is confusing because it recites "a 5' and 3' oligonucleotide"; it is not clear whether the cited expression represents one oligonucleotide or two oligonucleotides. Claim 1 is further indefinite because it recites "the 3' oligonucleotide with an appropriate size"; it is not clear for what purpose the size of the oligonucleotide would be appropriate, nor is it apparent what size(s) would be inappropriate. The metes and bounds are indefinite.

Claim 2 is indefinite in reciting "the 5' sequence has the sequence ..."; it is not clear whether "has" should be interpreted as open language, equivalent to "comprises" or closed language, equivalent to "consists of."

Claim 3 is similarly indefinite in reciting "the 3' sequence has sequence ..."; it is not clear whether "has" should be interpreted as open language, equivalent to "comprises" or closed language, equivalent to "consists of."

Claim 5 is indefinite because it recites "A method of determining the presence of ... in a sample comprising ..." but does not recite sufficient active process steps to result in a method of determining, nor does it recite any correlation between results obtained in any detecting step, for example, and the preamble or purpose of the claimed method.

Art Unit: 1648

Claim 7 is indefinite in reciting "appropriate size"; it is not clear for what purpose the size is intended to be appropriate. Claim 7 is indefinite and apparently has an omitted word because line 8 recites "... is with a fluorescent dye ...".

Claim 9 is indefinite in reciting "A set of oligonucleotides ..."; it is not clear how many oligonucleotides are in a set.

Claim 12 is indefinite because it recites "A method to screen for ..." but does not recite any active process steps.

Claim 13 is indefinite because it recites "A method to screen for ..." but does not recite any active process steps.

Claim 15 is indefinite in reciting "A set of oligonucleotides ..."; it is not clear how many oligonucleotides make up a set. Claim 15 is indefinite in reciting in lines 3 and 4, "the size ... should be ..."; it is unclear whether a size limitation is being claimed or suggested. Claim 15 is indefinite in reciting in line 6, "product should cover ..." and in lines 6-7, "in particular." It is unclear whether the material following "should cover" and "in particular" are being claimed or suggested.

Claim 16 is indefinite in reciting "A method to amplify ..." but does not recite any active process steps that would result in amplification.

Claim 17 is indefinite in reciting "A set of oligonucleotides ..."; it is not clear how many oligonucleotides make up a set. Claim 17 is indefinite in reciting in lines 3 and 4, "the size ... should be ..."; it is unclear whether a size limitation is being claimed or

Art Unit: 1648

suggested. Claim 17 is indefinite in reciting in line 6, "product should cover ...".

Claim 18 is indefinite in reciting "A method to amplify ..." but does not recite any active process steps that would result in amplification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/40193 to Stuyver et al., cited on PTO 892, attached. Stuyver et al. teach a method for detection of mutant HBV sequences in a sample comprising using primers, if necessary, to amplify

Art Unit: 1648

the region(s) that bear mutations of interest and using appropriate specific probes, preferably about 10-25 nucleotides long, corresponding to the region bearing the mutation and its wild-type counterpart for hybridizing to the nucleic acids that are in the sample or are amplified from the sample. Fig. 1 presents nucleotide sequences for a number of HBV strains; sheet 4 of Fig. 1 discloses the nucleotide sequences that encode HBsAg and indicates the location of codon 145. Stuyver discloses solid supports, including beads or chips, for immobilizing oligonucleotide probes, and also discloses that the oligonucleotides may be modified in order to facilitate immobilization or in order to improve hybridization. Such modifications include homopolymer tailing, coupling with reactive groups, or coupling such substances as biotin. Oligonucleotides to be used as primers or probes may also be labelled. See, e.g., page 16, lines 5-20. Table 1, page 28, indicates examples of HBsAg primers (SEQ ID NO's 75, 76, 94, 104, 105) and probes for HBsAg codon 145 wild type and mutant sequences (SEQ ID NO's 77-82). Based on the teachings of Stuyver et al., it would have been obvious to one of ordinary skill in the art to have made and used primers for amplifying the codon 145 region for one or more HBV strains of interest and to have made, immobilized, and used probes for detecting the presence or absence of escape mutants in HBsAg codon 145 because Stuyver et al. suggests doing so. While the primers and probes disclosed by Stuyver are not identical to those instantly claimed, it would have been obvious to one of ordinary skill in the art to have selected other, similar, HBsAg primers and probes that include the flanking regions of codon 145 and the sequences that encode the wild type and the escape mutant codon 145

Art Unit: 1648


based on the extensive teachings of Stuyver and to have successfully detected the mutation of interest.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,955,598 to Birkenmeyer et al., cited on PTO 892, attached, discloses primers and a method for detecting a mutation in HBsAg codon 145 by amplifying and quantitatively detecting the nucleic acid sequences of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:00 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1648, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.


Donna C. Wortman, Ph.D.
Primary Examiner

March 15, 2001